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December 6, 1999

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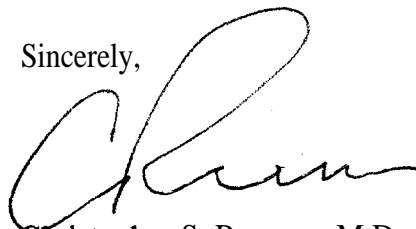
RE: Docket #97N-484S
Proposed Regulation of Bank Bone as Medical Device

To Whom It May Concern:

I am writing to register my opposition to the proposed FDA regulation of bone allograft. Bone is a natural substance, a tissue. Obviously, FDA regulations are critically important for the safety of bone; however, bone is not a medical device. Significant regulation of bone allograft as a medical device will likely cause a massive rise in the cost of surgery requiring bone grafting and will markedly diminish the supply of bone for use in medical procedures. As a neurosurgeon who performs many spine fusion procedures, I can attest that medical care will be greatly impacted and the proposed changes would lead to much poorer medical care for our patients.

I believe that the proposed changes are not in the best interest of patient care and safety. Thank you for considering my concerns regarding this matter.

Sincerely,



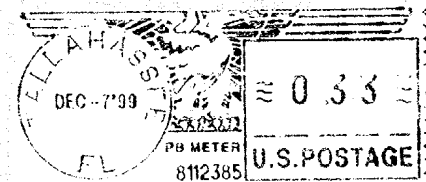
Christopher S. Rumana, M.D.

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